

Message

From: Chernoff, Neil [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2C8B0A1AA0347F7AB9245A7A5F28DE1-CHERNOFF, NEIL]
Sent: 8/22/2019 8:18:36 PM
To: Watkins, Andrew M. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35899b1060874a059646cec155abf669-Watkins, Andrew M.]
Subject: FW: IOAA/Program Office Requested Manuscript Revisions - ORD-032261 Lang et al.
Attachments: PFESA BP2 8_15_19_Rodan.docx; Boone Sci Total Enviorn 653_359 2019.pdf

From: Hines, Ronald <Hines.Ronald@epa.gov>
Sent: Thursday, August 22, 2019 10:32 AM
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Cc: Rogers, John M. <Rogers.John@epa.gov>; Lau, Chris <Lau.Christopher@epa.gov>; Buckley, Timothy <Buckley.Timothy@epa.gov>; Watkins, Tim <Watkins.Tim@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>
Subject: IOAA/Program Office Requested Manuscript Revisions - ORD-032261 Lang et al.

Good morning,

As all of you should be aware, I sent the ORD-032261 Lang et al. manuscript to the ORD IOAA to initiate Advance Notification on August 19, 2019. On the evening of August 20, I received a series of concerns on the Introduction section of the manuscript from Bruce Rodan. PFAS is a high-profile subject and often the IOAA has greater insights into possible Regional and Program Office sensitivities than we do in the Laboratories and Centers. I subsequently had direct communication with Gino Scarano and Tala Henry in OPPT regarding some of the statements in the Introduction concerning TSCA, as well as with Bruce Rodan and Jeff Frithsen to clarify some of their concerns. I have attached a copy of the manuscript with Rodan's concerns in track changes and comments. The concerns that need to be addressed before the IOAA will re-initiate the Advance Notification process are as follows:

You make the statement that: "Concern about PFASs has resulted in national, state, and global regulations and voluntary advisory levels. (ITRC, 2018)." (my underline) There are no such global regulations. Under the Stockholm Convention, for member nations, there are annexes to eliminate the "production and use" of PFOS and now PFOA. The United States is not a Party, hence the sensitivity to the term "global regulations". Please strike "global regulations" from this sentence.

In my earlier comments, I had suggested you use the number in the EPA PFAS Action Plan for the number of PFAS in commerce, but you elected to use a number from an OECD summary report instead. The number provided in the EPA PFAS Action Plan is 602 commercially active compounds and 621 commercially inactive. The total of both, 1,223, is consistent with the number provided in the 2018 OECD summary report which relied on PFAS compounds listed in chemical inventories from several nations. This manuscript is an EPA publication. I have no issue with you including the OECD number, but you should also cite the OPPT number that was published in the EPA PFAS Action Plan (EPA 823R18004, 2019). I suspect the discrepancy is how OCED is defining PFAS in their summary report.

You make the following statement: "1,1,2,2-tetrafluoro-2-[1,1,1,2,3,3-hexafluoro-3-(1,1,2,2-tetrafluoroethoxy)propan-2-yl]oxyethane-1-sulfonic acid (PFESA-BP2 CAS #749836-20-2) has not been

reviewed under the US Toxic Substance Control Act (TSCA) because it is only known to exist as a by-product of manufacturing Nafion polymer.” This is not an accurate statement. As part of TSCA, OPPT does evaluate by-products (sometimes referred to as residuals) of manufacturing or presumed degradates if they have concerns. In addition, some by-products may be on the TSCA inventory. OPPT did check and PFESA-BP2 is NOT on the TSCA inventory, but you cannot make the blanket statement that no manufacturing by-products are regulated under TSCA. Please reword as follows: **Because 1,1,2,2-tetrafluoro-2-[1,1,1,2,3,3-hexafluoro-3-(1,1,2,2-tetrafluoroethoxy)propan-2-yl]oxyethane-1-sulfonic acid (PFESA-BP2 CAS #749836-20-2) is a byproduct that has no commercial purpose, a pre-manufacture notice was not required, which would have been considered in the review under the US Toxic Substance Control Act (TSCA) (EPA PFAS Action Plan, EPA 823R18004, 2019).**

You have included the following two sentences: “Until 2017, wastewater at a North Carolina fluorochemical manufacturer (Chemours) was treated on-site with traditional methods, which are not known to effectively remove PFASs. (Gallen, Eaglesham, Drage, Nguyen, & Mueller, 2018; NCDEQ, 2015; Zhang et al., 2013) The lack of sufficient treatment resulted in the discharge of many different PFAS by-products into the Cape Fear River.” Please make this a more generic statement as follows: **“Traditional wastewater treatment processes, including those used by the North Carolina fluorochemical manufacturer, Chemours, are not effective in removing PFAS (Gallen et al. 2018, Zhang et al. 2013, Boone et al. 2019). The lack of sufficient treatment has resulted in the discharge of many different PFAS into water sources, including the discharge of PFAS and PFAS by-products into the Cape Fear River.”** Please do not use the NCDEQ 2015 citation. This citation is a permit and does not specify which treatment method actually was being used (it only provides a list of possible treatment options) nor provides any quantitative data on specific releases, i.e., quantifies amounts actually released versus amounts in untreated water. I have recommended you include the Boone et. al. 2019 paper as that is a recent EPA study that specifically addresses the question of PFAS removal during water treatment in the United States and complements the studies in Australia and China.

You make the statement: “Since by-products of chemical manufacturing not used for a commercial purpose are not assessed under TSCA, these compounds were freely released into the environment without any knowledge about their effects on wildlife and/or human health.” First, the use of “since” is not grammatically correct; “since” always refers to time. In this instance, you are describing a causal relationship and as such, the correct word is “because”. Second, for the same reasons outlined above, this is an overstatement and the causal statement is not accurate. Please consider re-wording as **“Depending on the situation, some by-products of chemical manufacturing not used for commercial purposes may not be assessed under TSCA. In those cases, the by-products may be released into the environment without an evaluation of possible effects on wildlife and/or human health.”**

You have included a paragraph in the introduction on detected water levels of PFESA-BP2 but fail to include any statement as to why this information is important and relevant to the current manuscript. Regarding the Buckley 2017 report, this study was not peer reviewed, but is a report to the North Carolina DEQ that has been made publicly available. Transparency regarding the accuracy of the numbers reported in the current manuscript is important. Please re-word as follows: **In 2012, two PFESA byproducts (i.e. PFESA-BP2 and perfluoro-3,6-dioxo-4-methyl-7-octene-1-sulfonic acid (PFESA-BP1 CAS #29311-67-9)) were detected in North Carolina’s Cape Fear River, downstream of an industrial manufacturing facility. (Strynar et al., 2015) In a September 2017 publicly available report to the North Carolina Department of Environmental Quality , the United States Environmental Protection Agency (USEPA) used a non-targeted analysis to estimate PFESA-BP2 concentrations in Chemours discharge and the Cape Fear River downstream of manufacturing as 45,200 ng/L and 2,075 ng/L, respectively. (Buckley, 2017). These reported PFESA-BP2 concentrations were provided as estimates because a PFESA-BP2 standard was unavailable at that time and as such, these concentrations assume that the mass spectrometer responded to the non-targeted analyte as**

if it were GenX [2,3,3,3-Tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)-propanoic acid, PFPrOPrA, CAS #13252-13-6], for which a standard was available. The report suggests such estimates are accurate to within 10-fold of the estimated value. In July 2017, North Carolina's Brunswick County drinking water provider (H2Go) began bi-weekly sampling for PFESA-BP2, with concentration estimates ranging from non-detectable (ND) to 134 ng/L in their finished drinking water. (H2Go, 2018) North Carolina's Department of Environmental Quality (NCDEQ) reported PFESA-BP2 in private wells near the industrial manufacturing facility with concentrations up to 125 ng/L. (NCDEQ, 2018). With the availability of an authentic standard provided by the manufacturer, subsequent studies corroborated PFESA-BP2 contamination in finished drinking water (Hopkins et al. 2018), but also in 99% of serum samples from research volunteers from this same region (Kotlarz, 2018). These studies demonstrate relatively high levels of PFESA-BP2 contamination in water sources within the Cape Fear River Basin, as well as the wide-spread presence of this compound in human serum samples from this same region.

Please take advantage of the EPA PFAS Action Plan as a citation to strength statements such as: **Given the potential health effects of PFASs (EPA PFAS Action Plan, EPA 823R18004, 2019)...**

On lines 220 to 222 or the Results and Discussion, you have included the comparison between the observed rat serum levels at the lowest dose tested and the reported human serum sample levels. However, this comparison should be reiterated in the Summary as it is an important observation. Please rephrase the Summary to include: **There were no adverse effects detected at the 0.04 and 0.4 mg/kg-day dose compared to the control group and at the lowest dose (0.04 mg/kg-day) serum levels were 100- to 200-fold higher than those reported in serum from humans exposed to PFESA-BP2 through drinking water.**

I have already previewed the above revisions with the IOAA and OPPT, so please strongly consider using the above suggestions verbatim. I am going to return the STICS record. When the revision is ready, please upload the document into the STICS record and route to me.

Please let me know if you have any concerns or questions.

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